

Package leaflet: Information for the user

Clindamycin 75 mg Capsules, hard
Clindamycin 150 mg Capsules, hard
Clindamycin 300 mg Capsules, hard

Clindamycin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Clindamycin is and what it is used for
2. What you need to know before you take Clindamycin
3. How to take Clindamycin Capsules
4. Possible side effects
5. How to store Clindamycin Capsules
6. Contents of the pack and other information

1. What Clindamycin is and what it is used for

Clindamycin Capsules contain clindamycin which is an antibiotic used in the treatment of serious bacterial infections.

2. What you need to know before you take Clindamycin

Do not take Clindamycin Capsules:

- if you are allergic to clindamycin, lincomycin or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clindamycin Capsules if:

- you have diarrhoea, or usually get diarrhoea when you take antibiotics, or have ever suffered from problems with your stomach, or intestines. If you develop severe, or prolonged, or bloody diarrhoea during, or after using Clindamycin Capsules, **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.
- you suffer from problems with your liver.
- you suffer from problems with your kidneys (see below).
- you suffer from asthma, eczema or hayfever.
- you develop any severe skin reactions or hypersensitivity to Clindamycin Capsules.

Acute kidney disorders may occur. Please inform your doctor about any medication you currently take and if you have any existing problems with your kidneys. If you experience decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath, or nausea you should contact your doctor immediately.

Clindamycin does not get into the brain and is therefore not suitable for treating serious infections in and around the brain. Your doctor may need to give you another antibiotic if you have these infections.

Other medicines and Clindamycin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- erythromycin (an antibiotic).
- muscle relaxants used for operations (neuromuscular blockers).
- oral contraceptive pills. You should use extra contraception such as condoms whilst taking Clindamycin and for seven days after taking Clindamycin.
- warfarin or similar medicines – used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- CYP3A4 or CYP3A5 inducers like rifampicin may impact effectiveness of the medicine.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine

Breast-feeding

Tell your doctor if you will be breast-feeding while taking Clindamycin Capsules as clindamycin may be passed into breast milk. Your doctor will decide if Clindamycin Capsules are appropriate for you. If you continue to take Clindamycin Capsules, you should stop breast-feeding.

Driving and using machines

No effects on the ability to drive or use machines have been seen with Clindamycin Capsule.

Clindamycin Capsules contain lactose

This medicine contains lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Clindamycin Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Clindamycin Capsules should always be swallowed whole with a full glass of water.

Adults and Elderly Patients

The recommended dose is between 150 and 450 mg (1 to 3 capsules) every 6 hours, depending on the severity of your infection.

Use in children

This medicine is used for children who are able to swallow capsules. The recommended dose in children is between 3 and 6mg per kg of bodyweight every six hours, depending on the severity of the infection. Your doctor will work out the number of capsules that your child should have.

Long term use of Clindamycin Capsules

If you have to take Clindamycin Capsules for a long time, your doctor may arrange regular liver, kidney and blood tests. Do not miss these check-ups with your doctor.

Long term use can also make you more likely to get other infections that do not respond to Clindamycin treatment.

If you take more Clindamycin Capsules than you should

If you accidentally take too many Clindamycin Capsules contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Clindamycin Capsules left or not. Do not take any more capsules until your doctor tells you to.

If you forget to take Clindamycin Capsules

If the forgotten dose is just a few hours late, use it straight away. If it is nearly time for your next dose miss out the forgotten one. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Clindamycin Capsules

If you stop taking the medicine too soon your infection may come back again or get worse. Do not stop taking Clindamycin Capsules unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you develop:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever).
This is an uncommon side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation or pseudomembranous colitis.
- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, dizziness, swelling of the eyelids or face or lips or throat or tongue, rash or itching (especially affecting the whole body).
- blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
- yellowing of the skin and whites of the eyes (jaundice).
- Potentially life threatening skin rashes:
 - a widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes or genitals, known as Stevens-Johnson syndrome, or a more severe form with extensive peeling of the skin (more than 30% of the body surface) known as *toxic epidermal necrolysis*,
 - a rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP),
 - skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - *erythema multiforme*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) and can be severe and life-threatening.
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

Other possible side effects may include:

Common (may affect up to 1 in 10 people):

- abnormal liver function tests (poor liver function)
- pain in the stomach / abdomen, diarrhoea.

Uncommon (may affect up to 1 in 100 people)

- feeling sick or being sick
- rash- characterized by a flat red area on the skin that is covered with small bumps, hives.

Frequency cannot be estimated from the available data:

- infection inside and around the vagina
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridium difficile*.
- effects on your blood system: reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- changes in the way things taste
- inflammation of the lining of the oesophagus (gullet), open sores or lesions in the lining of the oesophagus (gullet)
- yellowing of the skin and whites of the eyes (jaundice)
- red or scaly skin (exfoliative dermatitis), red measles-like rash (rash morbilliform), itching.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clindamycin Capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Clindamycin Capsule contains**

The active substance is clindamycin . Each capsule contains clindamycin hydrochloride equivalent to 75 mg, 150 mg or 300 mg of clindamycin.

The other ingredients are lactose monohydrate, maize starch and talc.

The 75 mg capsule shell contains Gelatin, Sodium Laurilsulfate , Brilliant Blue (E133), Erythrosine (E127) and Titanium dioxide (E171).

The 150 mg capsule shell contains Gelatin, Sodium Laurilsulfate, Iron Oxide Black (E172), Iron Oxide Red (E172), Erythrosine (E127) and Titanium dioxide (E171).

The 300 mg capsule shell contains Gelatin, Sodium Laurilsulfate, Brilliant Blue (E133), Erythrosine (E127) and Titanium Dioxide (E171).

The Printing Ink contains Shellac, Black Iron Oxide (E172), Potassium Hydroxide (E525) and Titanium Dioxide (E171)

What Clindamycin Capsules look like and contents of the pack

Clindamycin 75 mg is hard gelatin capsule (dimension 14 mm), red-violet cap printed 'RENATA' in white and off-white to light cream body printed 'Q 75' in black containing white crystalline powder.

Clindamycin 150 mg is hard gelatin capsule (dimension 18 mm), raspberry coloured cap printed 'RENATA' in white and off-white to light cream body printed 'Q 150' in black containing white crystalline powder.

Clindamycin 300 mg is hard gelatin capsule (dimension 21 mm), red-violet cap printed 'RENATA' in white and off-white to light cream body printed 'Q 300' in black containing white crystalline powder.

Clindamycin Capsules are available in the following pack sizes:

75 mg: 24 capsules

150 mg: 20, 24, 30, 40 and 100 capsules

300 mg: 16, 24, 30 and 32 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Renata Pharmaceuticals (Ireland) Limited
12 Crowe Street,
Dundalk,
Co. Louth,
Ireland, A91 NN29

Distributed by:

Azure Pharmaceuticals Ltd
Blackrock
Co Louth
Ireland

Manufacturer:

ALTERNO LABS d.o.o.
Brnčičeva ulica 29
Ljubljana-Črnuče, 1231
Slovenia

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland Clindamycin 75/150/300 mg Capsules, hard

This leaflet was last revised in April 2024